



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENT
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. Box 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

AUG 11 2003

David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RECEIVED

JAN 14 2004

OPLA

remailed

Dear Mr. Read:

The attached application for patent term extension of U.S. Patent No. 4,927,814 was filed on July 14, 2003, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, BONIVA™ (ibandronate), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)872-9411 (facsimile).

Karin Ferriter

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: George W. Johnston
Hoffman-La Roche Inc.
Patent Law Department
340 Kingsland Street
Nutley NJ 07110

2004 E-0444

LET 1



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENT
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. Box 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

AUG 11 2003

David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RECEIVED

JAN 14 2004

OPLA

remailed

Dear Mr. Read:

The attached application for patent term extension of U.S. Patent No. 4,927,814 was filed on July 14, 2003, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, BONIVA™ (ibandronate), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)872-9411 (facsimile).

Karin Ferriter

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: George W. Johnston
Hoffman-La Roche Inc.
Patent Law Department
340 Kingsland Street
Nutley NJ 07110